

BEST AVAILABLE COPY

**Amendments to the Claims:**

This listing of claims will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

1-74. (Cancelled)

75. (Currently Amended) A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises a lipid; one or more pharmaceutically acceptable surfactants, wherein the surfactant comprises one or more phospholipids and one or more non-ionic surfactants, and wherein the non-ionic surfactant comprises a block copolymer of ethylene oxide and propylene oxide; one or more pharmaceutically acceptable humectants; and water.

76. (Previously Presented) A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises: a lipid comprising a fatty acid glyceride ester; one or more pharmaceutically acceptable surfactants; one or more pharmaceutically acceptable humectants; and water.

77. (Previously Presented) The composition of claim 76, wherein the fatty acid glyceride ester comprises a monoglyceride or a triglyceride.

78. (Previously Presented) The composition of claim 77, wherein the fatty acid glyceride ester comprises a medium chain C<sub>6</sub>-C<sub>12</sub> fatty acid glyceride ester.

79. (Previously Presented) The composition of claim 78, wherein the medium chain C<sub>6</sub>-C<sub>12</sub> fatty acid glyceride ester is a triglyceride of caprylic/capric acid.

80. (Previously Presented) A spermicidal composition comprising a gel-microemulsion comprising:  
an oil-in-water microemulsion, wherein the oil-in-water microemulsion comprises a lipid;  
one or more pharmaceutically acceptable surfactants;  
one or more pharmaceutically acceptable humectants; and  
water;  
and a polymeric hydrogel selected from the group consisting of  
natural gel-forming polymers selected from the group consisting of carrageenan, xanthan gum, gun karaya, gum acacia, locust bean gum, and guar gum; and  
synthetic gel-forming polymers.

81. (Previously Presented) The composition of claim 80, wherein the natural gel-forming polymers are selected from the group consisting of carrageenan and xanthan gum.

82. (Previously Presented) A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises:

a lipid;  
one or more pharmaceutically acceptable surfactants, wherein the surfactant comprises one or more non-ionic surfactants;  
one or more pharmaceutically acceptable humectants;  
water; and  
one or more preservatives selected from the group consisting of sodium benzoate, methyl parabens, propyl parabens, thimerisal, and sorbic acid.

83. (Previously Presented) The composition of claim 82, wherein the preservative is sodium benzoate.

84. (Previously Presented) A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises:

a lipid;

one or more pharmaceutically acceptable surfactants;

one or more pharmaceutically acceptable humectants;

and water,

wherein the composition has a viscosity in the range of about 200 to about 1000 centipoise.

85. (Previously Presented) A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises:

a lipid;

one or more pharmaceutically acceptable surfactants;

one or more pharmaceutically acceptable humectants;

and water,

wherein the composition has a submicron particle size in the range of about 30 to about 80 nm.

86. (Previously Presented) A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and about 0.5% to about 4% by weight of polymeric hydrogel, wherein the oil-in-water microemulsion comprises:

about 2% to about 25% by weight lipid;

about 3% to about 30% by weight surfactant of one or more pharmaceutically acceptable surfactants;

about 2% to about 24% of one or more pharmaceutically acceptable humectants;

and water;

about 0% to about 0.5% preservative.

87. (Previously Presented) The composition of claim 86, wherein the composition comprises:

in the range of about 6% to about 23% by weight lipid;  
in the range of about 4% to about 17% by weight surfactant;  
in the range of about 3% to about 12% humectant;  
in the range of about 1% to about 2% polymer gel; and  
in the range of about 0% to about 0.3% preservative.

88. (Previously Presented) The composition of claim 87, wherein the composition comprises:

in the range of about 8% to about 15% by weight lipid;  
in the range of about 8% to about 15% by weight surfactant;  
in the range of about 5% to about 10% humectant;  
in the range of about 1.2% to about 1.8% polymer gel; and  
in the range of about 0% to about 0.2% preservative.

89. (Currently amended) ~~A spermicidal composition comprising a gel microemulsion comprising an oil-in-water microemulsion and about 0.5% to about 2% by weight of polymeric hydrogel.~~ The composition of claim 86, wherein the oil-in-water microemulsion comprises:

about 2% to about 20% by weight lipid;  
about 4% to about 17% by weight of one or more pharmaceutically acceptable surfactants;  
about 5% to about 22% of one or more pharmaceutically acceptable humectants;  
and water;  
about 0.5% to about 2% by weight of polymeric hydrogel; and  
about 0.1% to about 0.3% preservative.

90. (Previously Presented) The composition of claim 89, wherein the composition comprises:

in the range of about 3% to about 10% by weight lipid;  
in the range of about 4% to about 10% by weight surfactant;

in the range of about 12% to about 19% humectant;  
in the range of about 0.8% to about 1.2% polymer gel; and  
in the range of about 0.15% to about 0.2% preservative.

91. (Currently amended) A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and about 1% to about 2% by weight of natural polymer gel, wherein the oil-in-water microemulsion comprises:

in the range of about 6% to about 23% medium chain C<sub>6</sub>-C<sub>12</sub> triglyceride;

in the range of about 3% to about 10% ethoxylated castor oil;

in the range of about 1.5 % to about 6% phospholipid;

in the range of about 1.5% to about 6% propylene glycol;

in the range of about 1.5% to about 6% polyethylene glycol; and

water; and about 0% to about 0.2% preservative

92. (Previously Presented) The composition of claim 91, wherein the composition comprises:

in the range of about 8% to about 15% medium chain C<sub>6</sub>-C<sub>12</sub> triglyceride;

in the range of about 5% to about 9% ethoxylated castor oil;

in the range of about 3 % to about 6% phospholipid;

in the range of about 3% to about 6% propylene glycol;

in the range of about 3% to about 6% polyethylene glycol;

in the range of about 1.2% to about 1.8% natural polymer gel; and

in the range of about 0.1% to about 0.2% preservative.

93. (Currently Amended) ~~The composition of claim 91~~ A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and about 1% about 0.6% to about 2% by weight of natural polymer gel, wherein the composition comprises:

in the range of about 2% to about 20% medium chain C<sub>6</sub>-C<sub>12</sub> triglyceride;

in the range of about 1% to about 10% ethoxylated castor oil;

in the range of about 0.2% to about 1% block copolymer of ethylene oxide and propylene oxide;

in the range of about 1 % to about 10% phospholipid;  
in the range of about 2% to about 22% propylene glycol;  
~~in the range of about 0.6% to about 2% natural polymer gel;~~ and  
in the range of about 0% to about 0.3% preservative.

94. (Currently Amended) The composition ~~of claim 91~~ of claim 93, wherein the composition comprises:

in the range of about 3% to about 10% medium chain C<sub>6</sub>-C<sub>12</sub> triglyceride;  
in the range of about 2% to about 5% ethoxylated castor oil;  
in the range of about 0.2% to about 0.8% block copolymer of ethylene oxide and propylene oxide;  
in the range of about 1 % to about 5% phospholipid;  
in the range of about 12% to about 19% propylene glycol;  
in the range of about 0.8% to about 1.2% natural polymer gel; and  
in the range of about 0% to about 0.2% preservative.

95. (Previously Presented) The composition of claim 91 further comprising one or more therapeutic agents.

96. (Previously Presented) The composition of claim 95 wherein the therapeutic agent comprises up to 10% by weight of the composition.

97. (New) The composition of claim 94, wherein the lipid is a triglyceride of caprylic/capric acid, and the natural polymer gel is xanthan gum.

98. (New) The composition of claim 92, wherein the lipid is a triglyceride of caprylic/capric acid, and the natural polymer gel is carrageenans.

99. (New) A process for preparing a pharmaceutical composition according to claim 75, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 75.

100. (New) The process of claim 99, wherein the composition has a viscosity in the range of about 200 centipoise to about 1000 centipoise.

101. (New) The process of claim 99, wherein the composition has a submicron particle size in the range of about 30 nm to about 80 nm.

102. (New) A process for preparing a pharmaceutical composition according to claim 76, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 76.

103. (New) The process of claim 102, wherein the composition has a viscosity in the range of about 200 centipoise to about 1000 centipoise.

104. (New) The process of claim 102, wherein the composition has a submicron particle size in the range of about 30 nm to about 80 nm.

105. (New) A process for preparing a pharmaceutical composition according to claim 80, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 80.

106. (New) The process of claim 105, wherein the composition has a viscosity in the range of about 200 centipoise to about 1000 centipoise.

107. (New) The process of claim 105, wherein the composition has a submicron particle size in the range of about 30 nm to about 80 nm.



108. (New) A process for preparing a pharmaceutical composition according to claim 84, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 84.

109. (New) The process of claim 108, wherein the composition has a submicron particle size in the range of about 30 nm to about 80 nm.

110. (New) A process for preparing a pharmaceutical composition according to claim 85, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 85.

111. (New) The process of claim 110, wherein the composition has a viscosity in the range of about 200 centipoise to about 1000 centipoise.

112. (New) A process for preparing a pharmaceutical composition according to claim 86, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 86.

113. (New) The process of claim 112, wherein the composition has a viscosity in the range of about 200 centipoise to about 1000 centipoise.

114. (New) The process of claim 112, wherein the composition has a submicron particle size in the range of about 30 nm to about 80 nm.

115. (New) A process for preparing a pharmaceutical composition according to claim 91, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 91.

116. (New) The process of claim 115, wherein the composition has a viscosity in the range of about 200 centipoise to about 1000 centipoise.

117. (New) The process of claim 115, wherein the composition has a submicron particle size in the range of about 30 nm to about 80 nm.

118. (New) A process for preparing a pharmaceutical composition according to claim 93, the process comprising:

- (a) combining surfactants, hydrophilic components, and lipids in a container;
- (b) mildly heating and mixing the combined the components until a clear and homogeneous microemulsion is formed;
- (c) removing the microemulsion from heat and allowing to cool to about room temperature;
- (d) adding two parts of a pre-prepared polymer dispersion to each part of microemulsion; and
- (e) mixing the polymer dispersion and microemulsion to form the composition of claim 93.

119. (New) The process of claim 118, wherein the composition has a viscosity in the range of about 200 centipoise to about 1000 centipoise.

120. (New) The process of claim 118, wherein the composition has a submicron particle size in the range of about 30 nm to about 80 nm.

121. (New) A method for inhibiting the motility of sperm, the method comprising:

- a) providing a spermicidal composition of claim 75; and
- b) contacting the sperm with the spermicidal composition.

122. (New) The method of claim 121, wherein the sperm is contacted with the spermicidal composition intervaginally.

122. (New) A method for inhibiting the motility of sperm, the method comprising:  
a) providing a spermicidal composition of claim 76; and  
b) contacting the sperm with the spermicidal composition.

123. (New) The method of claim 122, wherein the sperm is contacted with the spermicidal composition intervaginally.

124. (New) A method for inhibiting the motility of sperm, the method comprising:  
a) providing a spermicidal composition of claim 80; and  
b) contacting the sperm with the spermicidal composition.

125. (New) The method of claim 124, wherein the sperm is contacted with the spermicidal composition intervaginally.

126. (New) A method for inhibiting the motility of sperm, the method comprising:  
a) providing a spermicidal composition of claim 84; and  
b) contacting the sperm with the spermicidal composition.

127. (New) The method of claim 126, wherein the sperm is contacted with the spermicidal composition intervaginally.

128. (New) A method for inhibiting the motility of sperm, the method comprising:  
a) providing a spermicidal composition of claim 85; and  
b) contacting the sperm with the spermicidal composition.

129. (New) The method of claim 128, wherein the sperm is contacted with the spermicidal composition intervaginally.

130. (New) A method for inhibiting the motility of sperm, the method comprising:  
a) providing a spermicidal composition of claim 86; and  
b) contacting the sperm with the spermicidal composition.

131. (New) The method of claim 130, wherein the sperm is contacted with the spermicidal composition intervaginally.

131. (New) A method for inhibiting the motility of sperm, the method comprising:

- a) providing a spermicidal composition of claim 91; and
- b) contacting the sperm with the spermicidal composition.

132. (New) The method of claim 131, wherein the sperm is contacted with the spermicidal composition intervaginally.

133. (New) A method for inhibiting the motility of sperm, the method comprising:

- a) providing a spermicidal composition of claim 93; and
- b) contacting the sperm with the spermicidal composition.

134. (New) The method of claim 133, wherein the sperm is contacted with the spermicidal composition intervaginally.

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**